Section III. Remarks

Claims 20, 24, 27, 28, 31-34, and 36-38 have been amended herewith, and new claims 41-45 have been added. No new matter has been added within the meaning of 35 U.S.C. § 132.

B. Claim Rejections Under 35 U.S.C. § 112

In the November 9, 2005 Office Action, claim 24 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the term "and/or" was deemed to render unclear the scope of claimed material characteristic.

Claim 24 has been amended herewith to overcome this rejection. Withdrawal of the rejection of claim 24 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

C. Claim Rejections Under 35 U.S.C. § 102

1. Rejections Under § 102 Generally

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock*, 721, F.2d 1540, 220 USPQ 303 at 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). It is not enough that the prior art reference disclose all the claimed elements in isolation. Rather, "anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). Further, "[u]nder 35 U.S.C. § 102, anticipation requires that ... the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public." *Akzo, N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986).

2. Traversal of Rejections Based On U.S. 6,670,171 to Carll

In the November 9, 2005 Office Action, claims 20-21, 23-27, 29-36, and 38-40 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,670,171 to Carll ("Carll"). Such rejections are traversed by the present claims.

Carll discloses a collapsible and disposable mixing bag 105 matable with a headplate 125 from which an impeller 140 having a magnet-containing hollow flexible shaft is suspended. Carll, FIGS. 1-2 and related text. The magnet may be reused. Id., col. 2, lines 62-65. The bag is sealed to a circumferential edge of the headplate. Carll, col. 3, lines 10-14. Mixing is effected by placing the mixing bag on an **external magnetic stirplate** that imparts magnetic energy to the magnet disposed within the hollow shaft to cause the shaft and impeller to move, e.g., in an elliptical pattern. Carll, col. 4, lines 25-57. A restriction element such as an O-ring is disposed on the shaft to ensure *gentle* rotation of the impeller, so as to prevent shearing of cells disposed within the mixing bag. Id., col. 2, line 66 – col. 3, line 6. The bag includes outer edges or seams that allow the bag to be free-standing; alternatively, a solid base similar to the headplate could be used to ensure the upright stabilization of the bag. Carll, col. 3, lines 15-24.

Carll fails to teach or suggest the use of various features required by claims 20-21, 23-27, 29-36, and 38-40. For example, each of claims 20-21, 23-27, 29-36, and 38-40 require a mixing element **mechanically coupled to a motor**. Instead, Carll specifically teaches the use of an external magnetic stirplate that interacts *magnetically* with a magnetic mixing element disposed within the mixing bag. There is no mechanical coupling between a motor and a mixing element in a device according to Carll. A device according to Carll has limited utility since it imparts only limited mixing force to the contents of the bag due to the relatively weak magnetic interaction, and the mixing apparatus is not easily scalable to larger sizes and volumes as a result.

Carll further fails to teach a "support frame coupled to the mixing tank with at least one coupling element [and] defining a plurality of windows," as required by claims 31-32 and 34-36; instead, Carll teaches the use of integral outer edges or seams, or a solid base similar to the headplate, that are used to ensure the upright stabilization of the bag. No "coupling element" or "windows" are provided in these structures according to Carll.

For at least these reasons, Carll fails to disclose "each and every element of the claimed invention, arranged as in the claim[s], as required to support an anticipation rejection according to *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984). Accordingly, withdrawal of the rejections of claims 20-21, 23-27, 29-36, and 38-40 based on Carll is respectfully requested.

3. Rejections Based On U.S. 2003/0226857 to Bibbo

Claims 20-40 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0226857 to Bibbo, et al. ("Bibbo"). Such rejections are traversed by the present claims.

Bibbo discloses a mixing assembly including a flexible mixing bag 202, a mixer or impeller 204 configured to be disposed within the mixing bag 202, and an expandable tubular seal 206 configured to provide a fluid sealed connection between the mixing bag 202 and the mixer 204 – wherein a mixing shaft 208 extends through a tubular seal 206 into the mixing bag to engage the **mixer (impeller)** 204 **that directly contacts the contents within the bag**. Bibbo, ¶¶ 0113-0138 & FIGS. 11, 14A, 14B. Mixing is accomplished by selectively raising or lowering the mixer (or impeller) with, and/or rotating, the shaft. E.g., Bibbo, ¶¶ 135-140. Mixing bags according to

Bibbo are supported by the floor 110 and side walls 24 of a surrounding tank assembly 20. Bibbo, ¶ 0121.

Bibbo fails to teach or suggest the use of various features required by claims 20-40 as enclosed herewith. For example, the **claims require a sealed sleeve that serves as an isolation barrier** (or prevents contact) between a mixing element and the interior of a tank. **Bibbo discloses no such barrier-type sleeve**; instead, Bibbo teaches ***direct contact*** between a mixer impeller 204 and the contents of a tank. See, e.g., Bibbo, ¶135 & FIG. 11 ("[a]s mixer 204 begins to push downward ... the fluid pushes flaps 264 against retention screen 260 ... [and] downward movement of mixer 204 causes the fluid within compartment 220 to flow down, out, up, and around as shown by arrow 294 in FIG. 11."). This sleeveless, direct contact between mixer and contents to be mixed is clearly contrary to the isolation barrier functionality required by all of the pending claims.

Additionally, Bibbo fails to teach the use of a support frame having a plurality of windows, as required by claims 31-32 and 34-37; instead, Bibbo teaches the use of a tank to support the mixing bag. The use of a frame versus a tank to support a mixing bag offers numerous advantages, including reduced material requirements and cost, enhanced flexibility to rescale mixing operations for different production volumes, and enhanced visibility of the contents of the tank.

For at least these reasons, Bibbo fails to disclose "each and every element of the claimed invention, arranged as in the claim[s], as required to support an anticipation rejection according to *Lindemann, supra.* Accordingly, withdrawal of the rejections of claims 20-40 based on Bibbo is respectfully requested.

4. Rejections Based On U.S. Patent Application Publication No. 2002/0105856 to Terentiev

Claims 20-24, 27-28, 30-34, 36, 38, and 40 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent Application Publication No. 2002/0105856 to Terentiev ("Terentiev"). Such rejections are traversed by the present claims.

Terentiev discloses a mixing bag 12 containing a spiral-shaped rotatable flexible or rigid tube 22, 122 that serves as a mixer. The rotatable tube extends through a first seal 18, 118, and optionally a second seal 119, defined in a wall of the bag, and engages an external motor 20. Terentiev, FIGS. 1-2 and corresponding text, including ¶ 0019. The tube and seal are sterilized separately from the bag and then assembled. Terentiev, ¶ 0014. The bag is placed within a rigid container to provide structural support. Terentiev, ¶ 0017. A clamping mechanism may be provided for holding the bag about the seal. Terentiev, ¶¶ 0009, 0017& claim 3.

Terentiev fails to teach or suggest the use of various features required by claims 20-24, 27-28, 30-34, 36, 38, and 40. For example, Terentiev fails to teach a sealed sleeve that is welded to a mixing tank, as required by claims 20-24, 27-28, 30-34, 36, 38, and 40. The lack of any welded joint between the tube and seals is apparent from paragraph 0014 of Terentiev: "[o]nce the bag is filled with product under sterile conditions, the tube 14 and seal 18 are placed in position as shown in FIG. 1, thereby sealing the bag." Even the most optimistic reading of mere '*placement into position*' to accomplish sealing cannot be taken to teach a weld or 'welded' connection within the meaning of 20-24, 27-28, 30-34, 36, 38, and 40.

Additionally, Terentiev fails to teach the use of a support frame having a plurality of windows, as required by claims 31-32, 34, and 36; instead, Terentiev teaches the use of a rigid container 32 that holds and stabilizes the bag, and no windows are apparent. E.g. Terentiev, ¶ [0015} & FIG. 1. The advantages of a window-containing frame over a rigid tank have been discussed previously.

For at least these reasons, Terentiev fails to disclose "each and every element of the claimed invention, arranged as in the claim[s], as required to support an anticipation rejection according to *Lindemann, supra.* Accordingly, withdrawal of the rejections of claims 20-24, 27-28, 30-34, 36, 38, and 40 based on Terentiev is respectfully requested.

D. Claim Rejections Under 35 U.S.C. § 103

1. Rejections Under § 103 Generally

Three requirements must be met for a *prima facie* case of obviousness. First the prior art reference(s) must teach all of the limitations of the claims. M.P.E.P. § 2143.03. Second, there must be a motivation to modify the reference or combine the teachings to produce the claimed invention. M.P.E.P. § 2143.01. Third, a reasonable expectation of success is required. M.P.E.P. § 2143.02. In addition, the teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based on Applicant's disclosure. M.P.E.P. § 2143.

2. Rejections Based On Terentiev

Claims 25-26, 35, and 37 were rejected under 35 U.S.C. 103(a) as being obvious over Terentiev. Terentiev has already been discussed hereinabove. As pertinent to these rejections, Terentiev fails to teach a sealed sleeve that is welded to a mixing tank, as required by claims 25-26, 35, and 37 for the same reasons as discussed previously.

Since Terentiev fails teach all of the limitations of the claims, as required by M.P.E.P. § 2143.03 to support a *prima facie* case of obviousness, the rejection of claims 25-26, 35, and 37 cannot stand, and the withdrawal of such rejections is respectfully requested.

E. Patentability of New Claims 41-45

New claims 41-45 include one independent claim (claim 41) that requires, *inter alia*, a "mixing paddle contained within the sealed sleeve [that] is driven by the motor and is adapted to travel within the tank through a defined path at a nonzero angle relative to the central vertical axis [of the mixing tank]." This feature is clearly supported by Figure 6 and specification text corresponding thereto.

None of the cited references teach a motor-driven paddle adapted to travel within a mixing tank in the claimed manner. Carll is directed exclusively to a mixing bag driven by a mechanical stirplate. Bibbo teaches the use of an impeller mounted on rotatable mixing shaft that extends through an expandable tubular seal to directly contact the contents of a mixing bag, with the mixing shaft capable of moving linearly into or out of the mixing bag. Bibbo fails to teach or suggest angular deviation of the mixing shaft from a central axis of the tank. Similarly, although Terentiev teaches the use of a spiral-shaped rotatable tube impeller driven by a motor, the tube rotates solely about the central axis of the tank. Thus, an apparatus according to Terentiev not only fails to teach a mixing paddle within the meaning of claim 41, but also it fails to teach a mixing paddle adapted to travel within a tank through a defined path at a nonzero angle relative to the central vertical axis.

Claims 42-45 depend from claim 41, and therefore include all of the limitations of claim 41.

Since none of Carll, Bibbo, or Terentiev teach all of the limitations of new claims 41-45, such claims are in good form for allowance over the cited art.

G. Fee Payable for Added Claims

The originally-filed application included fees for 5 independent claims and 19 total claims, while the application as currently amended has 5 independent claims and 26 total claims. Since the basic filing fee includes up to 3 independent claims and 20 total claims, it is believed that excess claim fees corresponding to 6 total claims (calculated as 26 total claims as presently amended minus 20 total claims permitted for payment of the basic filing fee) x $50 = **$300**. Accordingly, fee payment in the amount of $1090.00 - including $300 for adding 6 total (dependent) claims, in addition to the RCE fee of $790 – is authorized to be charged in the enclosed Credit Card Form. If Applicant is mistaken in its calculation of the excess claim fees now payable, however, then any necessary excess claim fee is hereby authorized to be charged to deposit account number 08-3284 of Intellectual Property/Technology Law.

H. Discussion of Telephonic Interview Conducted On December 29, 2005

A telephonic interview between the undersigned and Examiner Soohoo was conducted on December 29, 2005. In the Interview Summary mailed on January 4, 2005, the undersigned was requested to summarize the substance of the interview.

In the interview, the undersigned discussed that welding the sleeve and tank would provide one potential basis for distinguishing the cited art. Regarding the Carll reference, the undersigned further discussed that the reference teaches the use of a magnetic stirplate, not mechanical coupling to a motor. Regarding the Bibbo and Terentiev references, the undersigned discussed that neither of these motor-driven devices teach the use of a sleeve that is welded to a mixing tank. Examiner Soohoo indicated that further consideration of the references would be warranted, and indicated that the term "sleeve" in the context of a "sleeve coupled with a tank to form a unified contiguous structure" might be interpreted in various ways. The undersigned indicated that adding an affirmative "welded" limitation to a sleeve joined to a tank should avoid a possibly unduly open interpretation of the term "sleeve."

New Power of Attorney

A new power of attorney (form PTO/SB/80) and an accompanying Statement Under 37 CFR 3.73(b) (form PTO/SB/96) are submitted herewith.

Conclusion

Claims 20-45 as now pending in the application are in form and condition for allowance. Issuance of a Notice of Allowance for the application is therefore requested. If any issues remain outstanding, incident to the formal allowance of the application, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same, in order that this application may be allowed and passed to issue at an early date.

Respectfully submitted,

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Enclosures:
- Replacement drawing sheet 8 of 10, inclusive of Figure 6 [1 pg]
- Power of Attorney (form PTO/SB/80) [1 pg]
- Statement Under 37 CFR 3.73(b) (form PTO/SB/96) [1 pg]
- Credit Card Form (form PTO- 2038) [1 pg]
- Request for Continued Examination (RCE) [1 pg]
- Return Postcard